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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,661	09/29/2003	Elof Eriksson	CEL.728.US	2357

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EXAMINER
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TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
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3773

MAIL DATE	DELIVERY MODE
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11/08/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/673,661	<b>Applicant(s)</b> ERIKSSON ET AL.	
	<b>Examiner</b> Melanie Tyson	<b>Art Unit</b> 3773	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This action is in response to applicant's amendment received on 24 August 2007.

Corrections made to the claims are accepted.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schutz (Patent No. 3,037,509) in view of Eriksson (Patent No. 5,152,757).

Schutz discloses a dermal tissue grafting system (see entire document) comprising a tissue particle harvester assembly (for example, see Figures 1 and 2) and a tissue particle collector (storage container 20). Schutz discloses the tissue particle harvester assembly comprises a harvester housing (10) having an interior space, or opening, a tissue-cutting tool (blade 92) proximal to the opening (for example, see Figure 6), and a drive means (for example, see column 6, lines 45-49; a drive motor).

Schutz further discloses the tissue-cutting tool (92) comprises a rotatable shaft (76) having a drive end (for example, see column 4, lines 52-56) and a tool end (74). Schutz discloses the tissue particle harvester is configured to cut the dermal tissue into minute particles of proper size, and further discloses collecting the tissue particles, processing the tissue sample (can add a coagulating or additive agent; for example, see Schutz column 3, lines 49-51), and applying the excised particles to a recipient area (for example, see column 1, lines 10-13 and 37-41). Schutz fails to disclose the tissue particle harvester assembly is configured to cut the dermal tissue particles into the particular size or range of sizes claimed, a chambered dressing, and applying the excised particles to the chambered dressing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to configure the assembly to cut the dermal tissue into particles ranging between 50 and 300 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to configure the assembly to cut the dermal tissue into particles with a median size of about 100 microns, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Eriksson discloses a system (see entire document). Eriksson teaches a chambered dressing (for example, see Figure 10), seeding the chambered dressing with collected tissue, and culturing the growth of a dermal tissue graft (for example, see

column 8, lines 1-5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the excised particles collected with the device of Schutz to a chambered dressing as taught by Eriksson in order to be able to control the wound healing process, thus enhancing wound healing (for example, see column 2, lines 2-4).

4. Claims 5-8 and 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schutz in view of Eriksson and Adamson et al. (Patent No. 6,391,034 B1).

Schutz discloses a system as described above, and further discloses a particle retriever (spray nozzle 18, which retrieves particles from the storage container 20), a flushing container (for example, see column 3, lines 51-55; supply containers provide a flushing fluid through conduits to help remove, or flush, tissue particles), and a drive motor (for example, see column 6, lines 45-49). Eriksson discloses a system as described above, and further discloses the chambered dressing, or graft cell, comprises a port (28) and a portion that is substantially transparent (24). Eriksson fails to disclose the specific size of the chambered dressing, or graft cell. However, Eriksson teaches that it is well known that the size and shapes of wounds vary significantly (for example, see column 21, lines 12-14). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a nanograft cell, as claimed in claim 10, in cases involving smaller wounds. Furthermore, a change in size is generally recognized as being within the level of ordinary skill in the art.

With respect to claims 5-8, Schutz in view of Eriksson fails to disclose the harvester housing has an adjustable orifice and drive end within the ranges claimed,

and that the tool end is capable of mounting a cutting drum. With respect to claims 10-20, Schutz in view of Eriksson fails to disclose the housing is configured to be removed from the tissue particle harvester assembly while the cutting tool is contained within the housing.

Adamson discloses a device that cuts and collects tissue (see entire document). Adamson teaches a harvester housing (for example, see Figures 1, 5, and 9; element 12) having an interior space (cavity 14), an orifice (top of cavity 14), and a port, a cutting tool comprising a rotatable shaft (48) having a drive end (52) for engaging a drive means (for example, see column 3, lines 22-24), wherein the harvester housing is configured to be removed from the tissue particle harvester assembly while the cutting tool is contained within the housing (i.e., is configured to be removed from the driver 42), a distance between the opening and cutting tool is adjustable (for example, see column 3, lines 28-34), and a tool end (rest of shaft 48) capable of mounting a cutting drum (for example, see Figures 7-10; cylinders 84 and 90 may be defined as rotary *drums*) with or without a tapered end, since changing the shape of an element involves ordinary skill in the art.

Adamson further discloses the depth of tissue removal is adjustable by an adjustment bracket (60; column 3, lines 28-34). It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the assembly such that the tissue-cutting surface projects through the orifice of the harvester in the range of about .01-.9mm, since it has been held that where the general conditions of a

claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

With further respect to claim 17, Adamson discloses many types of cutting tools. However, Adamson fails to disclose the cutting tool comprises a scallop hypo-tube. Applicant states on page 9 of the specification that "the cutting surface of a rotating drum type cutting tool can be practiced with any variety of different cutting features selectable by the ordinary skilled artisan" and cites a scallop hypo-tube as an example. Applicant has not disclosed that a scallop hypo-tube provides an advantage, is used for a particular purpose, or solves a stated problem. Therefore, it would have been obvious to modify the cutting surface of the rotating drum of Adamson to obtain the invention as specified in claim 17.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tissue grafting system of Schutz in view of Eriksson as taught by Adamson in order to be able to precisely control the depth of tissue removal (for example, see column 1, lines 48-52), and to be able to remove the housing and cutting tool from the driver, thus making it easier to clean the housing and cutting tool.

### ***Response to Arguments***

5. Applicant's arguments with respect to claims 1-9 filed 24 August 2007 have been fully considered but they are not persuasive. Applicant argues primarily that the prior art applied fails to disclose or render obvious each and every element claimed. Examiner respectfully disagrees.

Applicant argues that Shutz does not disclose or render obvious the particular size or range of sizes claimed. However, Shutz discloses cutting tissue into microscopic particles. It has been held that discovering the optimum or workable ranges, and discovering an optimum value of a result effective variable involves only routine skill in the art.

6. Applicant's arguments with respect to claims 10-20 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-



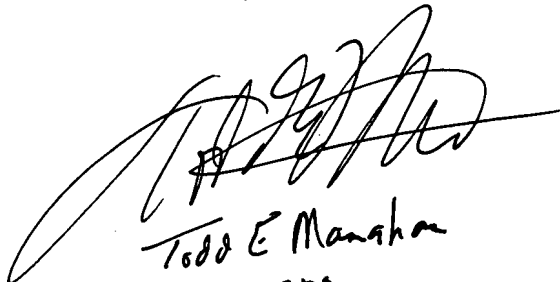
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9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson  
October 23, 2007



Todd E. Mangham  
SEP 3731